IN THE UNITED STATES DISTRICT COURT OF THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: DIGITEK PRODUCTS LIABILITY LITIGATION

MDL NO. 1968

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS COUNT EIGHTEEN OF THE MASTER CONSOLIDATED COMPLAINT FOR INDIVIDUALS

Plaintiffs, in opposition to the Defendants' Motion To Dismiss Count Eighteen of the Master Consolidated Complaint for Adoption by Individuals ("Master Complaint"), submit the following Memorandum.

INTRODUCTION

Plaintiffs' Master Consolidated Complaint for Individuals (hereinafter "Complaint") includes a cause of action under the Medicare as Secondary Payer Act that Defendants Actavis and Defendants Mylan now move to dismiss. Defendants' motion rests on the false proposition that Defendants' responsibility to pay a cost wrongfully incurred by Medicare must be established prior to the government filing suit. To read such requirements into the statute would displace the intent of Congress and undermine its efforts to protect and preserve the solvency of the Medicare Trust Fund. Because Plaintiffs have properly alleged a cause of action under a federal statute, Defendants' Rule 12(b)(6) motion to dismiss must fail.

STATEMENT OF FACTS AND LEGAL CLAIMS

I. Congress Enacted the Medicare as Secondary Payer Act in Order to Ensure that Those Responsible for Paying for the Medical Costs of Medicare Beneficiaries Would Pay Instead of American Taxpayers.

Medicare embodies the United States' commitment to the health care of seniors and the disabled with 44 million beneficiaries and total expenditures of $425 billion in 2007. 2008 ANNUAL REPT. OF THE BD. OF TRUSTEES OF THE FED'L HOSP. INS. AND FED'L SUPP. MEDICAL INS. TRUST FUNDS, *available at* http://www.cms.hhs.gov/ReportsTrustFunds/downloads/tr2008.pdf. Confronted with skyrocketing Medicare costs, Congress recognized in 1980 that those responsible for the payment of medical costs when people were injured (i.e. employers and liability insurers) engaged in the practice of allowing Medicare to pay the medical bills as the "primary payer" when an employee or a tort victim was older than 65. In order to curtail this practice, Congress enacted the Medicare as Secondary Payer Act (hereinafter "MSP"), making liability insurers and tortfeasors responsible as "primary" payers of injured persons' medical costs. 42 U.S.C. § 1395y(b)(2)(A). In practice, Medicare "conditionally" pays, and then seeks to recover payment from the responsible primary plan. § 1395y(b)(2)(B). Because Medicare's enforcement agencies seldom have the resources to seek full recovery of conditional payments, Congress created a private attorney general cause of action, carrying the traditional "double-damages" provision found in many *qui tam* actions in order to guarantee ***full*** enforcement. Despite Congress's efforts, and left on its current course, Medicare faces insolvency by 2019. O'Sullivan, Jennifer. Medicare: History of Part A Trust Fund Insolvency Projections, viewed at http://aging.senate.gov/crs/medicare14.pdf.

In attempt to rescue the trust fund, "Congress has repeatedly clarified and augmented the Government's powers to recoup conditional Medicare payments from primary sources," *United States v. Baxter Int'l,* 345 F.3d 866, 877 (11th Cir. 2003), and in fact has authorized the government and private attorneys general to sue a primary payer, prove the responsibility to pay,

and recoup Medicare's money, all in a single MSP action. § 1395y(b)(2)(B)(iii), (iv) & (3)(A). Several years ago, Congress clarified the MSP enforcement provisions by enacting the Modernization Act in order to resolve "disagreement among the courts as to [MSP's] proper interpretation" that had produced "counterintuitive and tortured results." *Brown v. Thompson*, 374 F.3d 253, 260-61 (4th Cir. 2004). This clarification of the Modernization Act was not regarded as a change in the law, but rather as a congressional declaration of what the law has always meant. *Id.* at 259-61.

Despite knowledge of difficulties in the manufacturing process for their pharmaceutical product, Defendants continued to market and sell those drugs for ingestion with the knowledge that the manufacturing process was prone to failure. Defendants have thus subjected thousands of Medicare beneficiaries to the risk of serious injury or death– the staggering cost of which has been imposed upon Medicare. In this fashion Defendants have relegated Medicare to the status of this tortfeasor's liability insurer – an immensely expensive deferral of medical costs to Medicare – precisely what MSP was enacted to correct and stop.

This MSP action represents Medicare's bill to the alleged tortfeasor. If Defendants are not responsible for payment, they will have ample opportunity to demonstrate why not. But Defendants should not be permitted to pervert the plain language of legislation that calls it to account in the first place. As demonstrated below, Defendants' attempts to do just that are unavailing, and their Motion to Dismiss must be denied.

II. The MSP Statute Establishes this Private Action against Defendants, a Primary Plan Responsible for Reimbursing Medicare for Disbursements Made in Connection with the Digitek Recall.

The "universally accepted" purpose of MSP is "to make Medicare's obligation secondary to that of designated primary obligors, with the intention of reducing federal health care costs." *Baxter*, 345 F.3d at 888. MSP was created by a series of amendments that makes Medicare the secondary payer where another entity is responsible to pay the beneficiary's medical expenses before Medicare. *Baxter*, 345 F.3d. at 877; *see also id.* at 877 & n.6 (summarizing evolution of MSP); *Cochran v. HCFA*, 291 F.3d 775, 777 (11th Cir. 2002). Such responsibilities to pay can be those of an employer's group health plan for an employed beneficiary's medical bills because that beneficiary got sick, § 1395y(b)(2)(A)(i), or those of a workmen's compensation scheme, no-fault insurance, automobile insurance, or a "liability insurance policy or plan" because that party has injured a beneficiary. § 1395y(b)(2)(A)(ii). An entity with such a responsibility is called a "primary plan." *Id.*

The relevant MSP provision here makes Medicare secondary to a "liability insurance policy or plan." § 1395y(b)(2)(A)(ii); *see Baxter*, 345 F.3d at 877 (automobile, liability, and no-fault insurance provision predates the MSP coverage of health insurance). As HCFA[1] has explained, liability insurance "is not a contractual arrangement between a beneficiary and an insurer; it is a contractual arrangement between a policyholder (i.e., the tortfeasor) and an insurer, which is intended to protect the policyholder from potential financial loss resulting from a tort for which he or she is responsible." 54 Fed. Reg. 41,716, 41,727 (Oct. 11, 1989).

[1] Health Care Financing Administration (the name of HCFA, the component of the Department of Health and Human Services responsible for administration of Medicare, has been changed to the Centers for Medicare and Medicaid Services. Because relevant regulations and other governmental documents were promulgated by HCFA under that name, in the brief we refer to that agency under the old acronym)

Plaintiffs, acting as an MSP private attorney general, filed this case to recover damages pursuant to the MSP statute of all Medicare expenditures resulting from their injuries suffered in connection with the recalled Digitek® (Digoxin). Compl. ¶ 175. Defendants come within the scope of the MSP regime because they are an MSP primary plan, in the form of a tortfeasor holding liability insurance policies. *See* § 1395y(b)(2)(A)(ii). Defendants had a responsibility to be the primary payer for these Digitek® recall-related medical expenditures because those expenditures were necessitated by Defendants' defective product.

STANDARD OF CONSIDERATION

When considering a motion to dismiss under Rule 12, a court must accept as true all material allegations of the complaint, and must construe the complaint in favor of the plaintiff. *Scheuer v. Rhodes,* 416 U.S. 232, 236, 94 S.Ct. 1683, 40 L.Ed.2d 90 (1974); *see Zinermon v. Burch,* 494 U.S. 113, 118, 110 S.Ct. 975, 108 L.Ed.2d 100 (1990); *Lambeth v. Board of Comm'rs,* 407 F.3d 266, 268 (4th Cir.), *cert. denied,* 546 U.S. 1015, 126 S.Ct. 647, 163 L.Ed.2d 525 (2005). "[A] district court may dismiss a complaint for failure to state a claim only if it appears beyond doubt that the plaintiff can prove no set of facts that would entitle him to relief." *Conley v. Gibson,* 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957). The issue is not whether a plaintiff will ultimately prevail, but whether the claimant is entitled to offer evidence to support the claims. *Revene v. Charles County Com'rs*, 882 F.2d 870, 872 (4th Cir. 1989). As Plaintiffs will demonstrate, this action is precisely what Congress authorized, and indeed intended, when it repeatedly clarified the expansive scope of the MSP regime in its application to alleged tortfeasors.

ARGUMENT

I.

BECAUSE PLAINTIFFS HAVE SUFFICIENTLY ALLEGED DEFENDANTS ARE A PRIMARY PLAN, PLAINTIFFS HAVE STATED A VALID MSP CLAIM

The Supreme Court has recently reaffirmed that Rule 8(a)'s "simplified notice pleading standard" merely requires a statement that " 'give[s] the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests.' " *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 512, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002) (quoting *Conley v. Gibson*, 355 U.S. 41, 47, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957)). Thus, while a complaint comprised solely of labels and conclusions is insufficient to satisfy this rule, specific facts, elaborate arguments, or fanciful language are not necessary. *Erickson v. Pardus*, 551 U.S. 89, 127 S.Ct. 2197, 2200, 167 L.Ed.2d 1081 (2007). In addition, MDL Courts have assessed the sufficiency of the Master Complaint with leniency. *In re Trasylol Prods. Liab. Litig.*, 2009 WL 577726, (S.D.Fla.,2009).

Section 1395y(b)(2)(B)(iii) of the MSP requires a primary plan to reimburse Medicare "if it is demonstrated" that the primary plan "has or had a responsibility" to make payment for an item or service. Via the Modernization Act, Congress amended the MSP to permit actions against "any or all entities that are or were required or responsible … to make payment … under a primary plan" – language that is broader than the prior statute that permitted such actions against "any entity." Congress intended by the broader scope of this language to permit a broader scope of actions for recovery under the MSP. Defendants come within the scope of the MSP regime because they have and had MSP "primary plans," in the form of liability insurance policies or plans. § 1395y(b)(2)(A)(ii).

Plaintiffs set forth Count Eighteen in the Master Complaint for Individuals seeking to recover under MSP, including a specific citation to 42 U.S.C. §1395y(b)(3)(A) which states:

> There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of *a primary plan* which fails to provide for primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A).

42 U.S.C. §1395y(b)(3)(A)(emphasis added). As the statute sets forth a cause of action "in the case of a primary plan", Plaintiffs have given Defendants fair notice of the basis of this claim for relief. There is simply no other way that Defendants could interpret this statute. As such, by including a claim for recovery under the MSP, Plaintiffs have sufficiently alleged that Defendants are a "primary plan". [2]

II.

BECAUSE PLAINTIFFS MAY ESTABLISH DEFENDANTS' RESPONSIBILITY TO REPAY MEDICARE IN THE CONTEXT OF THIS LAWSUIT, PLAINTIFFS HAVE STATED A VALID MSP CLAIM.

At the direction of the Court in Pre-Trial Order #11, Plaintiffs filed a Master Consolidated Complaint for Individuals in this MDL. One purpose of a Master Complaint is to set forth all potential claims within the scope of the MDL. Indeed, many MDL Courts require the filing of an Amended Complaint as an administrative tool to promote judicial economy. *See, e.g., In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 454 (E.D.La.2006) ("[A] master complaint is only an administrative device used to aid efficiency and economy and, thus, should not be given the status of an ordinary complaint.") (quoting *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 140-41 (E.D.La.2002)); *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 489 F.Supp.2d 932, 936 (D.C.Minn.2007) ("Consolidation of a master complaint is merely a procedural device designed to promote judicial economy, and, as such, it does not affect the rights of the parties in separate suits."). Therefore, Plaintiffs included all known potential cases

[2] In the alternative, Plaintiffs respectfully request leave to amend the Master Complaint in order to provide additional facts and allegations.

of action in the Master Complaint for Individuals, including Count Eighteen, which is a valid cause of action to be included in this MDL.

A. The History of MSP Legislation and Litigation Demonstrate that this Court Must Adjudicate the Government's Claim to Statutory Damages Via the Private Attorney General Provisions of MSP.

1. MSP Enforcement. Until 1984, there was no express enforcement provision in MSP. Nevertheless, it was recognized that MSP provided an implied right of action, and HCFA accordingly promulgated regulations setting out its enforcement regime. With respect to the liability insurance relevant here, HCFA's 1983 rule provided: "If payment is not received from the insurer or the responsible party, HCFA may bring an action against the insurer or the responsible party, and the beneficiary must cooperate in HCFA's action." 48 Fed. Reg. 14,802, 14,810 (April 5, 1983) (publishing 42 C.F.R. §405-324). A nearly identical provision governed reimbursement. *See id.* at 14,812 (publishing 42 C.F.R. §405.329); *see also Provident Life and Acc. Ins. Co. v. U.S.*, 740 F. Supp. 492, 506 (E.D. Tenn. 1990); *United States v. Blue Cross & Blue Shield of Michigan*, 726 F. Supp. 1517, 1521 (E.D. Mich. 1989). In 1984, the Deficit Reduction Act of 1984, Pub. L. No. 98-369, 98 Stat. "conferred on the Government a direct right of action to recover its payments from any entity which would be responsible for payment under a 'law, policy, plan or insurance,' and provided that the Government would be subrogated to the right of any individual or entity to receive payment." *Baxter*, 345 F.3d at 877; § 1395y(b)(2)(B)(iii) & (iv).

Two years later, in the Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, 100 Stat. 1874, Congress added the MSP private enforcement action, *Baxter*, 345 F.3d at 878, which, like the False Claims Act, 31 U.S.C. Section 3729 et seq. (hereinafter "FCA"), empowers "private attorneys general" to aid enforcement of MSP; that is, it "allow[s] individual citizens …

to sue in order to right an economic wrong done to the government." *Manning v. Utilities Mut. Ins. Co.*, 254 F.3d 387, 394 (2d Cir. 2001). Unlike an FCA action in which the successful relator gets a percentage of the recovery, Congress provided that a successful private MSP litigant secures double damages, half of which goes to Medicare to make it whole, and half of which the private attorney general keeps as a bounty in order to ensure maximum recoupment. *Compare* 31 U.S.C. § 3730(d) *with* 42 U.S.C. § 1395y(b)(3)(A).

2. The Modernization Act. Through the 1980s and 90s, courts struggled with varying interpretations of MSP. Notably, several Courts invited congressional intervention if MSP was not to be construed as they had opined. *See Mason v. American Tobacco Co.*, 346 F.3d 36, 43 (2nd Cir. 2003); *Thompson v. Goetzmann*, 377 F.3d 489, 503-04 (5th Cir. 2003). Via the Modernization Act, Congress accepted that invitation. The Modernization Act clarified the MSP's language governing reimbursement from a primary plan to make it clear that:

> A primary plan … shall reimburse [Medicare] for any payment … if it is demonstrated that such primary plan has or had a responsibility to make [that] payment …. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means.

Medicare Prescription Drug, Improvement and Modernization Act of 2003, §301(b)(2)(A), 117 Stat. 2066, 2222 (codified at § 1395y(b)(2)(B)(ii)) (also referred to as "Modernization Act.")Based upon the above, it is clear that Plaintiffs have stated a valid claim for relief under the MSP.

C. A Private AG May Demonstrate the Payment Responsibility in the Context of the MSP Action Itself.

The main thrust of Defendants motion appears to be that a claim under MSP cannot be brought simultaneously with, or in the same suit as, a tort action. Dr. Br. At 5. That theory fails under a reading of the statute and a review of Congressional intent.

1. The Text of MSP Does Not Support the Two-Lawsuit Theory.

Contrary to Defendants' position, the MSP statute's text and structure clearly indicate that Congress was establishing these MSP causes of action based on the government's ability to demonstrate a third party's responsibility to pay. The MSP paragraph in which "by other means" is found provides that a primary plan must reimburse Medicare "if it is demonstrated that such primary plan has or had a responsibility" to pay for a Medicare beneficiary's medical bills. § 1395y(b)(2)(B)(ii). The provision then continues that such a payment responsibility "may be demonstrated" by a judgment, settlement or "by other means." *Id.* Thereafter, MSP sets out the "Action by the United States," § 1395y(b)(2)(B)(iii), and the "Private cause of action," § 1395y(b)(3)(A). Congress included no language that suggests that the responsibility for payment could not be established in the "Action by the United States" or the "Private cause of action."

Defendants assert that MSP establishes a potential obligation to repay Medicare, but that Plaintiffs must first establish Defendants' liability for its defective products independent of this MSP action. Def. Br. At 6. Defendants, without citing specific language in the statute, illogically asserts that the MSP statute creates a cause of action, only to require that one of the elements of that cause of action must be proven in a separate, preceding case – thus requiring two lawsuits. This theory is simply an attempt to avoid what MSP plainly says. Indeed, MSP's enforcement provisions say nothing about a two-lawsuit notion. Both the government's right of action and the private attorney general action under the MSP are straightforward actions

designed "to recoup from the rightful primary payer … if Medicare pays for a service that was, or should have been, covered by the primary insurer." *Baxter*, 345 F.3d at 875; *see also* § 1395y(b)(2)(B)(iii) (authorizing the government to sue "any and all entities that are or were required or responsible … to make payment" (against which the government may recover double damages) and to sue "any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity."); § 1395y(b)(2)(B)(iv) (subrogating Medicare to the right of the Medicare beneficiary to have his medical bills paid by a third party); § 1395y(b)(3)(A) ("establish[ing] a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A)"); *Dow Corning*, 250 B.R. at 335-49 (explaining elements of an MSP action).

First, Medicare's interest under MSP is derivative of the responsibility of a third party to pay a Medicare beneficiary; if a third party is not responsible to pay a beneficiary's medical bills, no MSP issue arises. *See In re Dow Corning Corp*, 250 B.R. 298, 346 (Bank. E.D. Mich. 2000) (A "primary plan's potential liability flows entirely from its obligations to the Medicare beneficiary."). Second, MSP does not create that third party's responsibility to pay; it simply directs the flow of dollars to reimburse Medicare. Third, the MSP private right of action, like a suit under the FCA, is derivative of, or effects a partial assignment of, Medicare's interest in reimbursement. *See Manning*, 254 F.3d at 394 ("[B]oth [the FCA and MSP] allow individual citizens, as well as the government, to sue in order to right an economic wrong done to the government."); *Vermont Agency of Natural Res. V. United States*, 529 U.S. 765, 773 (2000). Fourth, nothing carves out a third party's primary payment responsibility from an MSP action (whether arising from tort or some other duty). Neither description in the MSP of the underlying

responsibility ("entities that are or were required or responsible" to pay, or a primary plan that "has or had a responsibility to make payment") suggests that in giving the government and a private attorney general the authority to sue, Congress withheld the authority to prove that third-party responsibility in the MSP lawsuit. The issue here is whether primary payment responsibility can be demonstrated, that is, proved, in an MSP action, not whether an MSP defendant can be held liable for a Medicare reimbursement simply on a plaintiff's allegations.

If Congress had intended that an MSP action could be brought only after a previous adjudication of third party responsibility, the legislation would have required that a primary plan reimburse Medicare only "if it *had been demonstrated* that such primary plan is responsible." *Cf. Sutton v. United Air Lines, Inc.*, 527 U.S. 471, 482 (1999) (relying on Congress' choice of verb tense to construe a statute); *Navarro v. Pfizer Corp*, 261 F.3d 90, 100-01 (1st Cir. 2001) (same). Congress's decision to use the present subjunctive tense ("if it is demonstrated") conveys the idea that the demonstration of third-party liability need not have been accomplished before the MSP action can be pursued; it can occur during the MSP action itself. This grammatical construction is entirely familiar. For example, courts frequently state that a particular outcome is required "if it is demonstrated" that a certain showing is made, meaning that the showing must be made presently – not that it must have been made in some earlier proceeding. *See, e.g.*, *People v. Pomykala*, 784 N.E.2d 784, 791 (Ill. 2003) ("An error in a jury instruction is harmless if it is demonstrated that the result of the trial would not have been different had the jury been properly instructed."); *Tuttle v. Eats and Treats Operations, Inc.*, 2005 U.S. Dist. LEXIS 15302 at 1-2 (D. Kan. May 23, 2005) ("Summary Judgment is proper if it is demonstrated that the movant is entitled to judgment as a matter of law on the basis of facts to which there is no genuine dispute.").

Congress's use of present subjunctive tense explains why the statute includes the phrase "such primary plan has or *had* a responsibility [.]" If Defendants' reading were correct, there would be no need to use both the present-tense term "has" and the past-tense term "had"; after all, under Defendants' reading, the tortfeasors' liability would already be a foregone conclusion, either through (1) a previous adjudication or (2) a settlement. Why then bother with both terms? The answer, of course, is that Congress's decision to include both terms makes perfect sense if an alleged tortfeasor's responsibility can be demonstrated in a third way – in the context of the MSP enforcement litigation itself.

Common sense confirms this grammatical analysis. When a statute gives someone a right of action to sue Joe when he has done "X," and says nothing more, it is commonly understood that the plaintiff must prove all the elements establishing that Joe has in fact done "X" when bringing that action. Put another way, when a statute authorizes a party to bring a lawsuit when a wrong has been committed or some act has occurred, it naturally speaks in just that way because when the plaintiff brings the case the wrong or act will already ***have*** occurred.

The law reflects this reality in that, by definition, being "liable" means: "Bound or obliged in law or equity; ***responsible***; chargeable; answerable; compellable to make satisfaction, compensation or restitution." Black's Law Dictionary, p. 915 (6th ed. 1990) (emphasis added). Thus, legal "responsibility" is in apposition to "liability." Of course, liability attaches not upon final judgment, but much earlier – upon completion of the negligent act and realization of damages. "[T]he rights and liabilities of the parties are fixed at the moment of the accident with respect to a cause of action sounding in tort." *In re Reading Co.*, 404 F. Supp. 1249, 1251 (E.D. Pa. 1975). The responsibility of a primary payer in tort arises when "all the elements of the

cause of action exist." *Smith v. Salish Kootenai College*, 387 F.3d 1048, 1054 (9th Cir. 2004); *see also Jobe v. ATR Marketing, Inc.*, 87 F.3d 751, 753 (5th Cir. 1996).

When Congress establishes a right of action to recover Medicare's money from such an entity that has primary payment responsibility due to a tort, then, that responsibility already exists, and an MSP suit can be brought directly against such a responsible primary payer, even if another court has not already ordered the payment of damages. In other words, the tort of battery is complete (and liability is triggered) when the unpermitted contact takes place, not when the tortfeasor refuses to pay for his misconduct. The statute's natural reading is that Plaintiffs will have to prove that the Defendants were responsible to pay for Medicare beneficiaries' medical bills because of their defective products. *See Dow Corning*, 250 B.R. at 343 ("Had the Government been pursuing an [MSP] action again the [liability] insurer, the Government would likely have been required to prove that the beneficiary was a tort victim of the insured and that the medical care paid for by the Government was necessitated by that tort.").

Moreover, in MSP Congress employed a model it had used before. For example, a public employee can be sued for damages for malicious prosecution under 42 U.S.C. § 1983, but that malicious prosecution (which is defined by state law) need not be first established in a separate lawsuit. Similarly, the false character of a claim under the FCA often rests on attributes that could have been independently adjudicated, but the FCA has not been construed to require such an adjudication before an FCA case can be brought. *Cooper v. Blue Cross and Blue Shield of Florida*, 19 F.3d 562, 564-65 (11th Cir. 1994); *see also McNutt ex rel. United States v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005) (violation of the Anti-Kickback Statute can form a basis for an FCA claim); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017 (S.D. Tex. 1998) (same); *United States*

ex rel. Plumbers & Steamfitters Local Union No 38 v. C W Roen Constr. Co., 183 F.3d 1088, 1092 (9th Cir. 1999) (false certification that workers have been paid in compliance with the Davis-Bacon Act gives rise to FCA liability.).

Given all of the relevant text of MSP, it is not unreasonable to conclude that a primary responsibility to pay can be demonstrated in an MSP recovery action. *See Atlantic Fish Spotters Ass'n v. Evans*, 321 F.3d 220, 224 (1st Cir. 2003) ("When the words of a statute neither create ambiguity nor lead to an entirely unreasonable interpretation, an inquiring court need not consult other aids to statutory construction."). Furthermore, the plain wording of the statute indicates that Congress intended to include all "means" available to an Article III court of establishing responsibility, but listed "judgment" and "settlement" separately so that a primary payer could not, in the context of an MSP action against it, re-litigate a finding of liability from a prior, collateral action.

2. The Regulatory History of the MSP Does Not Support the Two-Lawsuit Theory.

Regulators agree with Plaintiffs' view. Courts "look to the well-reasoned views of the agencies implementing a statute, which constitute a body of experience and informed Judgment to which courts and litigants may properly resort for guidance." *Santiago Clemente v. Executive Airlines, Inc.*, 213 F.3d 25, 30 n.2 (1st Cir. 2000) (quoting *Bragdon v. Abbott*, 524 U.S. 624, 642 (1998). *See also Olmstead v. Zimring*, 527 U.S. 581, 598 (1999); *United States v. Mead Corp.*, 533 U.S. 218, 230-31 (2001). There is a rich regulatory history of MSP dating back to the early 1980s, which suggests an aggressive MSP enforcement posture utterly at odds with the two-lawsuit theory.

Strikingly, even before Congress enacted an express MSP right of action, HCFA proposed regulations that claimed such a right for Medicare, reflecting HCFA's conclusion

that it could pursue the MSP claim directly against "the person responsible for the injury," that is, it could sue the alleged tortfeasor. 47 Fed. Reg. 21,103 21,105 (May 17, 1982). As HCFA explained:

> Liability claims are usually filed against the individual or other entity ***that allegedly caused the injury*** rather than against a liability insurer. When the claim is settled or adjudicated, usually after protracted negotiation and possible litigation, a liability insurer may pay all or only part of the claim. A beneficiary who obtained payment, or a judgment or settlement, would be required to reimburse the program….If the beneficiary did not pursue the claim, HCFA could institute its own action.

Id. (emphasis added). Unmistakably, HCFA could sue the "entity that allegedly caused the injury" to a Medicare beneficiary as part of MSP recovery.

HCFA reiterated the same perspective in its final rule. *See, e.g.*, 48 Fed. Reg. at 14,804 ("With respect to liability claims, if a direct action were necessary, HCFA would usually bring the action against both the insurer and the responsible party."). The rule provided that HCFA could make a conditional Medicare payment for "treatment of an injury or illness that was allegedly caused by another party and … the beneficiary has filed, or has the right to file, a liability claim against the other party." *Id.* at 14,810 (publishing 42 C.F.R. §405.324(a)(1)). Then, "[I]f payment is not received from the insurer or the responsible party, ***HCFA*** may bring an action against the insurer or the responsible party." *Id*. (publishing 42 C.F.R. §405.324(a)(3)(iii)). Clearly, the rule equates the party who "allegedly caused" the injury with the "responsible" party who can be sued for MSP recovery. Moreover, the rule included an identical payment and recovery mechanism for health insurance. *Id*. at 14,812 (publishing 42 C.F.R. §405.329). In short, HCFA understood its powers to include a direct MSP recovery action against any ***third*** party responsible to pay a Medicare beneficiary's medical bills in which HCFA could prove that responsibility to pay.

To take into account the subsequent additions of explicit provisions for the government's right of action, its subrogation to a Medicare beneficiary's rights, and the private right of action, HCFA restructured its regulations in 1989, creating the format for MSP regulations still operative today. The 1989 revision brought together into one section provisions for MSP recovery actions against ***different*** types of primary plans:

> 411.24 Recovery of conditional payments
>
> (b) Right to initiate recovery. HCFA may initiate recovery as soon as it learns that payment has been made or could be made under workers' compensation, any liability or no-fault insurance, or an employer group health plan.
>
> * * *
>
> (e) Recovery from third parties. HCFA has a direct right of action to recover from any entity responsible for making primary payment. This includes an employer, an insurance carrier, plan, or program, and a third party administrator.

54 Fed. Reg. at 41,738 (publishing 42 C.F.R. §411.24(b) & (e).

Moreover, the regulations reflect HCFA's understanding that an MSP recovery action by its very nature requires proof of the underlying payment responsibility, providing that, "[i]f HCFA takes action to recover conditional payments, the beneficiary must cooperate in the action," 54 Fed. Reg. at 41,738 (publishing 42 C.F.R. §411.23(a)), and "[i]f HCFA's recovery action is unsuccessful because the beneficiary does not cooperate, HCFA may recover from the beneficiary." *Id*. (publishing 42 C.F.R. §411.23(b)). If an MSP recovery action could not adjudicate the underlying payment responsibility to the Medicare beneficiary, these provisions requiring the cooperation of a beneficiary would have been unnecessary.

Thus MSP's regulatory history confirms that the adjudication of third-party primary payment responsibility has never been carved out of MSP recovery actions. The Modernization Act was not needed to "expand" MSP so that adjudication of alleged torts could occur in an MSP

action and certainly that Modernization Act text was not written to scale back on MSP recovery actions to exclude such adjudications.

3. In the Event the Court Finds this Claim is Not Yet Ripe, a Stay of the MSP Claim is the Appropriate Remedy.

Plaintiffs included an MSP count in the Master Complaint for Individuals. There is no controlling case law requiring a second lawsuit as Defendants' maintain. Recognizing that this Court may find that while the underlying MSP claim is valid, the claim is not yet ripe, Plaintiffs respectfully submit it would be premature to rule on this motion at this point in time. In cases where one party's liability is derivative of the liability of the other defendants, or one claim is derivative of another claim, district courts have bifurcated the claim and stayed discovery as to it. *Carter v. Baltimore County, Maryland*, 95 Fed.Appx. 471 (4th Cir. 2004); *Minyard Enterprises, Inc. v. Southeastern Chemical & Solvent Co*., 184 F.3d 373, (4th Cir. 1999). This approach is well recognized in situations where and insurer is joined with an insured party; "[c]laims against insurer under unfair claim settlement practices provision of West Virginia Unfair Trade Practices Act may be joined with underlying third-party personal injury action against insured, as long as claims are bifurcated and proceedings against insurer, including discovery, are stayed until underlying claim has been "ultimately resolved," which means that any and all appeals have been exhausted. W.Va.Code, 33-11-4(9). *Maher v. Continental Cas. Co.*, 76 F.3d 535, (4th Cir. 1996). As such, in the event the Court deems it necessary, Plaintiffs request the Court to stay this decision, or bifurcate this claim, until such time that Defendants "responsibility" has been "demonstrated".

CONCLUSION

Based on the foregoing points and authorities, Plaintiffs respectfully request that this Court **DENY** Defendants' Motion to Dismiss.

Dated: May 19, 2009

Respectfully submitted,

On Behalf of the Plaintiffs' Steering Committee

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CERTIFICATE OF SERVICE

I hereby certify that on May 19, 2009, I electronically filed the foregoing "Response in Opposition to Defendants' Motion to Dismiss Count Eighteen of the Master Consolidated Complaint for Individuals" with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

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